APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,883	12/11/2001	Andrew Thomas Fagan	343355600034	2367

			EXAMINER
24325	7590	07/27/2006	KOPPIKAR, VIVEK D

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ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>08 June 2006</u>.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-36* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-36* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail. Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1.   Claims 1-36 have been examined in this application. This non-final communication is in

response to the "Amendment" and 'Remarks" sections filed on June 8, 2006. The examiner

would further like to thank the applicants and the attorney for the applicants for the telephonic

interview conducted on July 19, 2006.

Claim Rejections - 35 USC § 103

2.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

3.   Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent

Number 5,949,999 to Song in view of US Patent Number 6,917,944 to Prasad and in further

view of US Patent Number 7,054,823 to Briegs and in further view of US Patent Application

Number 2003/0028549 to Hartel.

a database that stores data collected from the biomedical development phases (Song: Col.

5, Ln. 38-42);

at least one first graphical user interface connected to the database that collects data

during the first biomedical development phase (Song: Col. 5, Ln. 27-31) (Song discloses that its

software is adapted for product development processes regulated by the FDA which the

examiner interprets to include biomedical or pharmaceutical processes); and

Song has the capability of producing and generating an audit trail of data (Song: Col. 2, Ln. 10-23).

Song does not teach the following limitations and features which are taught by Prasad:

the database further including a first metadata data structure that describes the data collected during a first biomedical development phase (Prasad: Col. 4, Ln. 29-35);

wherein the metadata data structure of the first graphical user interface is defined based at least in part upon the first metadata data structure so that the first graphical user interface collects data points as well as first metadata that is to be stored within the first metadata data structure, said first metadata describing the collected data points (Prasad: Col. 3, Ln. 49-60),

wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent development phase (Prasad: Col. 3, Ln. 8-18).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the system of Song with the aforementioned features from Prasad with the motivation of developing a system having the ability to process requests for reconfiguring different data repositories as recited in Prasad (Col. 2, Ln. 8-14).

The combined teachings of Song in view of Prasad in view of Briegs in view of Hartel do not teach the following limitation which is taught by the combined teachings of Briegs and Hartel:

wherein at least a portion of the data structure is configured to provide information for a subsequent biomedical development phase (Briegs: Figure 50 and Col. 39, Ln. 9-12). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Prasad in view of Briegs in view of Hartel

with the aforementioned teachings from Briegs with the motivation of having a means to inform

the user that subsequent trials (visits) are still remaining, as recited in Briegs (Col. 39, Ln. 4-12).

In Briegs the "indication of whether any data is yet to be collected" does not relate to

metadata structures, however, Hartel teaches the step of configuring metadata structures as

needed (e.g. for subsequent phases) to provide their specific properties (Hartel: Section [0019]).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to

have modified the combined teachings of Song in view of Prasad in view of Briegs in view of

Hartel and Briegs with the aforementioned teachings from Hartel with the motivation of giving a

user a means of customizing metadata structures, as recited in Hartel (Section [0019]).

(B)   As per claim 2, in the combined system of Song in view of Prasad in view of Briegs in

view of Hartel the biomedical development phases include phases selected from the group

consisting of discovery phase, clinical studies phase, Food and Drug Administration (FDA)

approval phase, product release phase, and combinations thereof (Song: Col. 2, Ln. 10-23).

(C)   As per claims 3-8, 20-21 and 34, the combined system of Song in view of Prasad in view

of Briegs in view of Hartel teaches metadata data structures but does not expressly teach the

specific data recited in claims3-8, 20-21 and 34; however, these differences are only found in the,

non-functional descriptive material and are not functionally involved in the steps recited nor do

they alter the recited structural elements. The recited method steps would be performed the same

regardless of the specific data. Further, the structural elements remain the same regardless of the

specific data. Thus, this descriptive material will not distinguish the claimed invention from the

prior art in terms of patentability, *see In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404*

(Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included these data types recited in the above mentioned claims with the motivation of providing a more comprehensive data analysis system to be used in the biomedical development phase.

(D)   As per claim 9, the combined system of Song in view of Prasad in view of Briegs in view of Hartel teaches a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase (Prasad: Col. 3, Ln. 8-17 and Col. 4, Ln. 29-35). The motivation for modifying Song with these aforementioned features from Prasad is the same as that was set forth in the rejection of Claim 1.

(E)   As per claim 10, the combined system of Song in view of Prasad in view of Briegs in view of Hartel comprises:

at least one second graphical user interface connected to the database that collects data during the second biomedical development phase (Song: Col. 5, Ln. 27-31), wherein structure of the second graphical user interface is defined based at least in part upon the second metadata data structure so that the second graphical user interface collects data points as well as second metadata that is to be stored within the second metadata data structure, said second metadata describing the collected data points (Prasad: Col. 3, Ln. 8-17 and Col. 4, Ln. 29-35),

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the system of Song with the aforementioned features from Prasad with the motivation of developing a system having the ability to process requests for reconfiguring different data repositories as recited in Prasad (Col. 2, Ln. 8-14).

The combined teachings of Song in view of Prasad in view of Briegs in view of Hartel do not teach the following limitation which is taught by the combined teachings of Briegs and Hartel:

wherein at least a portion of the second metadata is determined based upon an issue which arises in a biomedical development phase that occurs approximately subsequently to the second biomedical phase (Briegs: Figure 50 and Col. 39, Ln. 9-12). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Prasad in view of Briegs in view of Hartel with the aforementioned teachings from Briegs with the motivation of having a means to inform the user that subsequent trials (visits) are still remaining, as recited in Briegs (Col. 39, Ln. 4-12).

In Briegs the "indication of whether any data is yet to be collected" does not relate to metadata structures, however, Hartel teaches the step of configuring metadata structures as needed (e.g. for subsequent phases) to provide their specific properties (Hartel: Section [0019]). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Song in view of Prasad in view of Briegs in view of Hartel and Briegs with the aforementioned teachings from Hartel with the motivation of giving a user a means of customizing metadata structures, as recited in Hartel (Section [0019]).

(F)   As per claim 11, in the combined system of Song in view of Prasad in view of Briegs in view of Hartel the second biomedical development phase is a clinical studies phase (Song: Col. 10-23)(Note: Product development phases in the biomedical industry involve clinical studies), wherein the second metadata data structure includes data that specifies interrelationships between tests conducted during the second biomedical development phase (Prasad: 8-18). The

motivation for modifying Song with these aforementioned feature from Prasad is the same as that

set was forth in the rejection of Claim 1.

(G)   As per claims 12-15, in the combined system of Song in view of Prasad in view of Briegs

in view of Hartel data links exist between the first metadata stored in the first metadata data

structure and the second metadata stored in the second metadata data structure in order to form

an audit trail (Prasad: Col. 3, Ln. 8-18 and Song: Col. 19-23). (Note: Relational databases, as

disclosed by Prasad, provide data links between various metadata sets).

In Song the audit trial is used during an FDA approval phase to determine a biomedical

product development trail associated with the first and second biomedical development phases

(Song: Col. 2, Ln. 10-23). (Note: The FDA audits the records dealing with various product

development processes in part to approve the products).

The examiner takes the position that the first metadata is used during an FDA approval

phase to determine how tests were conducted during the first biomedical development phase,

wherein the second metadata is used during the FDA approval phase to determine how tests were

conducted during the second biomedical development phase. (Note: The purpose of the FDA

audit is the examine the methodology of the tests).

(H)   As per claims 16-18, in the combined system of Song in view of Prasad in view of Briegs

in view of Hartel the examiner takes the position that the first biomedical development phase in

Song is the discovery phase and the second development phase is the clinical studies phase (the

discovery phase is commonly the first phase in a development process and the clinical studies

phase is commonly the second phase in a development process), wherein at least a portion of the

first metadata data structure is determined based upon an issue that arises in the FDA approval

phase. (Song: Col. 2, Ln. 10-23). Song does not teach that the issue that arises in the FDA approval process that defines at least a portion of the first metadata data structure is an FDA requirement that patients be tested who are taking a predetermined medication. The examiner takes the position that it is well known in the biomedical and pharmaceutical industry that patients who are taking a predetermined medication be tested and at the time of the invention it would have been obvious for one of ordinary to have added this criteria to the development process in order to prevent patients who are taking a predetermined medication from having adverse reactions and in order to isolate or at least identify those patients which may be an aberrational affect on the data obtained from the biomedical development phase.

(I)   As per claim 19, the examiner takes Official Notice that it is well known in the art to select the third party from another company division, a different company, the FDA or combinations thereof. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have selected these particular individuals with the motivation of having a pool of participants who are readily available to participate in the study.

(J) As per claims 22-29, these claims repeat features previously addressed in the rejection of claims 1-21 and are rejected on the same basis.

(K)   As per claim 30, in the combined system of Song in view of Prasad in view of Briegs in view of Hartel the identifier is a uniform resource locator (URL) that identifies data and metadata as associated with the first biomedical project and owned by the first company (Prasad: Claim 16). The motivation for making this modification to the system of Song is the same as that was set forth in the rejection of Claim 1.

(L)   As per claims 31-33, the examiner takes Official Notice that it is well known in the art to

limit or allow the access rights of another entity to certain portions of the data and that access to

portions of this data is protected by user names and passwords. At the time of the invention, it

would have been obvious for one of ordinary skill in the art to have added these features in the

combined system of Song in view of Prasad in view of Briegs in view of Hartel with the

motivation of preventing unauthorized users from gaining access to the data and also for

preventing an entity participating in the biomedical development phase from gaining access to

data after its role in the biomedical phase had been completed.

(M)   As per claims 35, this claim repeats features previously addressed in the rejection of

claims 1-33 and are rejected on the same basis.

(N)   As per claim 36, the combined system of Song in view of Prasad in view of Briegs in

view of Hartel further comprises:

        a second metadata data structure contained within the database that describes the data

collected during a second biomedical development phase, said second biomedical development

phase occurring approximately after the first biomedical development phase (Prasad: Col. 4, Ln.

29-35);

        a third metadata data structure contained within the database that describes the data

collected during a third biomedical development phase, said third biomedical development phase

occurring approximately after the second biomedical development phase (Prasad: Col. 4, Ln. 29-

35);

        a fourth metadata data structure contained within the database that describes the data

collected during a fourth biomedical development phase, said fourth biomedical development

phase occurring approximately after the third biomedical development phase (Prasad: Col. 4, Ln.

29-35),

wherein the data links associate genomic data with data contained within at least the

second metadata data structure (Prasad: Col. 3, Ln. 13-18).

The motivation for modifying Song with these aforementioned features from Prasad is

the same as that was set forth in the rejection of Claim 1.

wherein FDA approval is sought for a biomedical product directed to people with first

genetic characteristics, said first genetic characteristics being identified based upon analysis of

the genomic data that is associated with the data in the second metadata data structure (Song:

Col. 2, Ln. 10-23). (Note: Song does not specifically recite that the products which are being

developed are products for which FDA approval is sought for a biomedical product directed to

people with first genetic characteristics, the first genetic characteristics being identified based

upon analysis of the genomic data that is associated with the data in the second metadata

structure. However, the examiner takes the position that it is well known in the biomedical

industry to develop products for people with certain genetic characteristics (e.g. people who

carry a gene for a certain disease) and at the time of the invention, it would have been obvious

for one of ordinary skill in the art to have modified the combined system of Song in view of

Prasad in view of Briegs in view of Hartel with this limitation with the motivation of providing

products to people who carry a given gene for a disease so that the chances that these people will

develop this disease will be reduced if they used newly developed biomedical product.

Response to Arguments

4.   Applicant's arguments filed on June 8, 2006 with respect to claims 1-36 have been

considered but are moot in view of the new ground(s) of rejection.
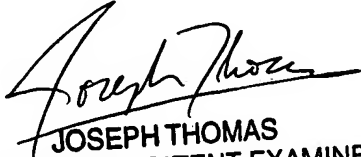
Conclusion

5.   Any inquire concerning this communication or earlier communications from the

examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109.

The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's

supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for

this group are either (571) 273-8300 or (703) 872-9326 (for official communications including

After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information

Retrieval (PAIR). Information regarding the status of an application can be obtained from the

(PAIR) system. Status information for published applications may be obtained from either

Private PAIR or Public PAX. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel

free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

7/24/2006

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER